UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,344	11/23/2001	George Jackowski	2132.096	5805

21917 7590 07/28/2005

MCHALE & SLAVIN, P.A.
2855 PGA BLVD
PALM BEACH GARDENS, FL 33410

EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,344	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 39-46* is/are pending in the application.

4a) Of the above claim(s) *39-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal matters

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 04, 2005 has been entered.

Response to Amendment

3. Claims 1, 39 and 44-46 have been amended as requested in the amendment of Paper filed on April 04, 2005. Claims 1 and 39-46 are pending in the instant application.

4. Claims 39-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Claim 1 is under examination in the instant office action.

5. The amendment to the claims filed on April 04, 2005 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121, as amended on June 30, 2003

(see *68 Fed. Reg. 38611,* Jun. 30, 2003) with respect to claims 39-46 . Specifically, the correct status of claims 39-46 is "Withdrawn". Appropriate correction is required.

6. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

8. Applicant's arguments filed on April 04, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claim 1, as amended, is rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record in section 5 of Paper mailed on July 18, 2003 and reasons set forth below. The instant application has provided a description of a peptide. The instant application does not disclose a specific biological role for this peptide, or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Claim 1 is drawn to an isolated biopolymer marker peptide consisting of amino acid residues 2-18 of SEQ ID NO: 1. Briefly, the instant specification describes the finding of a specific fragment of apolipoprotein J precursor protein, which is SEQ ID NO: 1, residues 2-18,

in serum samples patients diagnosed with Alzheimer's disease. This finding is further extrapolated into an assertion that peptide 2-18 of SEQ ID NO: 1 could be useful as a marker for Alzheimer's disease. The state of the art at the time of filing is such that it does not recognize any specific association of the fragment 2-18 of a peptide of SEQ ID NO: 1 with Alzheimer's disease. The instant specification, as originally filed fails to provide any factual evidence or scientific reasoning to support a conclusion that a fragment 2-18 of SEQ ID NO: 1 is specifically associated with any disease, including Alzheimer's disease.

It is stated on page 46, last paragraph of the instant specification that "Figures 1, 3 and 5 are photographs of a gel which is indicative of the presence/absence of the marker in disease vs. control and, in cases where the marker is always present, the relative strength, e.g. the up or down regulation of the marker relative to categorization of disease state is deduced". First, the instant specification fails to explain the relationship between a peptide 2-18 of SEQ ID NO: 1 and "particular disease state". Next, there is no explanation presented at the time of filing as to what constitutes a "biopolymer marker". Is it "the presence/absence" of the peptide 2-18 of SEQ ID NO: 1 that is indicative of a disease? Or "the up or down regulation of the marker relative to categorization of disease state"?

A specification can meet the legal requirements of utility and enablement for a new peptide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new peptide, or a well-established utility for the claimed peptide would be readily apparent to the skilled artisan. A hypothetical example may serve to clarify. For example, a hypothetical specification discloses that a claimed peptide is expressed in colon cancer and not expressed in healthy colon tissue. The hypothetical specification does not

disclose the biological activity of the polypeptide encoded by the polynucleotide. The claimed peptide in the hypothetical example would not be rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as it has utility and is enabled as a colon cancer marker. Alternatively, a hypothetical specification could disclose that a claimed peptide is expressed at specific altered levels in colon cancer as compared to healthy colon tissue. One skilled in the art would immediately recognize that the peptide in hypothetical example would be useful as a colon cancer marker. However, such is not the fact pattern here. The instant specification discloses that "a biopolymer marker which is strongly present in a normal individual, but is down-regulated in disease is predictive of said disease; while alternatively, a biopolymer marker which is strongly present in a disease state, but is down-regulated in normal individuals, is indicative of said disease state" (page 11 of the instant specification). Thus, it appears that in order to practice the claimed invention a skilled practitioner would have to engage in significant further research to determine if a peptide 2-18 of SEQ ID NO: 1 is absent or present or strongly present in all or any tissue samples of a person suspected having Alzheimer's disease, or is up- or down-regulated in disease in order to establish if the claimed peptide could be used as a marker for Alzheimer's disease. However, it is a matter of law that the claimed invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention.

Therefore, to accept Applicant's claim for a "biopolymer marker" irrespective of any recitation of intended use in the claim or lack of support for asserted utility to use the claimed peptide for diagnosis of Alzheimer's disease, would be comparable to use the peptide 2-18 of SEQ ID NO: 1 as an object of future research. It was just such applications that the court appeared to be referring to when it expressed the opinion that all chemical compounds are

"useful" to the chemical arts when this term is given its broadest interpretation (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). Because the steroid compound which was the subject of that decision had a known structure and molecular weight it could have readily been employed as a molecular standard at that time. Further, because that compound was a hydrocarbon it certainly could have been employed in the well-known process of combustion for purposes of lighting and/ or the generation of heat. The generation of heat by combustion of hydrocarbons certainly was and remains an important process. Irrespective of such obvious utilities, the court still held that the compound produced by the process at issue in *Brenner v. Manson* did not have a specific and substantial utility.

Applicant's arguments traversing the enablement requirement in Response submitted on April 04, 2005 are answered in so far as they are relevant with respect to the instant utility rejection. It is further noted that Applicant refers to the alleged amendment to claim 1 "to recite that the isolated peptide is linked to Alzheimer's disease" (middle at page 20 of the Response). However, claim 1, as presented, does not contain any reference to Alzheimer's disease, therefore, Applicant's arguments with respect to this intended amendment are moot.

At pages 22-29 of the Response, Applicant presents explanations of the results presented in Figure 1 and argues that "a skilled practitioner clearly would be able to distinguish between a normal sample and an Alzheimer's disease sample". Applicant's arguments have been fully considered but are not persuasive for the following reasons. To clarify the Examiner's position, it was never disputed that the claimed protein 2-18 of SEQ ID NO: 1 could be potentially linked to Alzheimer's pathology since it has been found in serum sample of a patient suspected of having Alzheimer's disease (the state of the art remains clear and sound that the definitive diagnosis of

Alzheimer's disease could be made only during postmortem examination of patient's brain, see reasons of record in previous office actions). However, the worker of skill in the art readily appreciates that in order to serve as a marker, the claimed peptide must be either present or absent or present at altered levels in tissue sample in order to be useful as a diagnostic tool. At page 30 of the Response, Applicant submits that "[t]he pending claims do not recite that the claimed peptide is diagnostics for any pathological condition, including Alzheimer's disease". While it is true that the claim, as amended, does not include any limitations as to what the claimed peptide is diagnostic for, the issue at hand remains that in order to satisfy the utility requirement under 35 U.S.C. 101, the claimed peptide must have a specific and substantial credible utility. If the instant peptide 2-18 of SEQ ID NO: 1 is not "diagnostics for any pathological condition, including Alzheimer's disease", then it is not obvious why it is termed as a marker. Applicant argues that "the intended purpose of the invention is to provide improved, alternative means for diagnosis of Alzheimer's disease which can be easily be performed by an untrained individual without the need for additional testing" (top at page 31 of the Response). However, as fully explained earlier and also in previous office actions of record, the instant specification provides no evidence that the instant peptide 2-18 of SEQ ID NO: 1, which was found to be "differentially expressed between Alzheimer's disease and age matched normal" (middle at page 32) in limited number of serum samples of patients suspected of having Alzheimer's disease, would have any specific and substantial utility for diagnosis of Alzheimer's disease. There appears to be no disagreement with Applicant's argument regarding the value of proteomics research in identifying proteins that "may prove to be a useful drug target or diagnostic marker" (top at page 33); moreover, Applicant's cited articles all appear to relate to

importance of scientific research to identify potential and possible future diagnostic tools, and the Examiner does not dispute that too.

In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), the court specifically stated that "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion". The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. In the instant case the claimed peptide 2-18 of SEQ ID NO: 1 is only useful for further research to establish it's specific and substantial utility.

To grant Applicant a patent encompassing an isolated fragment of a naturally occurring human protein, which is not readily usable in it's current form, would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" *Brenner v. Manson, Ibid*). To grant Applicant a patent on the claimed peptide based solely upon an assertion that the protein is linked to Alzheimer's disease is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted.

Thus, since the instant specification does not disclose a credible "real world" use for the isolated fragment 2-18 of SEQ ID NO: 1 in currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

July 24, 2005